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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,670	01/05/2006	Thomas Gore	I-2002.025 US	4798

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EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/539,670	GORE ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments to claims 1 and 6-13 and new claim 27, received June 14, 2006 are acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 refers to "Minute virus of canine (MVC, CPV-1) and Canine Parvovirus (CPV-2)". The claim language fails to accurately describe and particularly point out the claimed invention. The subject matter of the claimed invention is not clear as to the difference between Minute virus of canine and canine parvovirus, CPV-1 and CPV-2. If applicant intends the claim to indicate that MCV and canine parvovirus – 1 (CPV) are alternative names for the same virus, then the claim should be amended to more clearly indicate this.

Claim 6 reads "the group consisting of live, attenuated live, killed, and any combination of the aforementioned". The claim language fails to accurately describe and distinctly claim the subject matted of the claimed invention. The claim reads that

the antigen is "live", "attenuated live" or "killed". It is unclear what the intended difference is for "live" and "attenuated live", and suggests the possible interpretation of the "live" virus as wild-type virus. Since vaccine compositions do not ordinarily contain infectious wild-type virus, the metes and bounds of the claimed invention are unclear and the claim is indefinite.

Claims 8-13 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a vaccine and a method of vaccinating a puppy wherein the titer of the virus at one or two week post whelp is greater than 1:32 or 1:128. The claims as presented do not particularly point out if the titers are measured in the bitches or puppies. The claims should be amended to clarify the subject matter of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Audonnet et al. (US Patent No: 6,159,477). The claimed invention is drawn to a multivalent vaccine comprising a first antigen, a second antigen and a third antigen, wherein each antigen, first, second and third are different.

Audonnet et al. teaches a recombinant canine herpes virus expressing multiple antigens, i.e. canine distemper, rabies virus, canine parvovirus, parainfluenza virus, etc. This multivalent vaccine can be administered to dogs and especially puppies.

Therefore, Audonnet teaches the limitations of the instant invention of a multivalent canine vaccine. For purposes of the art rejection, the intended use of a composition for administration to the mother in order to generate maternal antibodies has not been given patentable weight for the present rejection.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by either of Waner et al., (The Veterinary Journal, 1998, Vol. 155, No. 2, p. 171-175) or Poulet et al. (The Veterinary Record, June 2001, Vol. 148, No. 22, p. 691-695, abstract only).

The claimed invention is drawn to a method of vaccinating a puppy against at least one of canine herpesvirus (CHV), canine rotavirus (CRV), and canine parvovirus (CPV) by administering the vaccine to the bitch prior to whelp, and comprising the steps of administering a vaccine to the bitch prior to whelp and allowing the puppies to nurse.

Waner et al. teaches a method of vaccination with a commercial vaccine with canine parvovirus and distemper virus administered to pregnant bitches at 30-40 days of gestation (p. 172). Therefore Waner teaches the limitations of the claim of a method to vaccinate a puppy comprising at least one canine virus and one antigen then administering to a bitch prior to whelping.

Poulet et al. teaches a method of vaccinating a puppy against canine herpesvirus comprising administering a vaccine to the pregnant bitch. Poulet teaches that the vaccine was protective in the pups. Therefore Poulet teaches the limitations of the claimed invention of a method to vaccinate a puppy comprising at least one canine virus and one antigen then administering to a bitch prior to whelping.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 14-16, and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Poulet et al., Mochizuki et al., (Journal of Veterinary Medical Science, 2001, Vol. 65, No. 5, p. 573-575), Miller et al. (US Patent

No: 6,057,436), Schwartz et al., (Virology, Oct. 2002, Vol. 32, No. 2, p. 219-223), and Pratelli et al., (Journal of Veterinary Medicine B, 2000, Vol. 47, p. 273-276).

The claimed invention is drawn to a multivalent vaccine comprising a first antigen, a second antigen and a third antigen, wherein an effective amount of maternal antibody to each antigen is transferred to pup when nursed, wherein each antigen, first, second and third are different, wherein the first, second or third antigen is canine herpesvirus (CHV), canine rotavirus (CRV), or canine parvovirus (CPV), wherein the CPV is Minute virus of canine (MCV) or CPV-2, the vaccine wherein the first antigen is CHV, the second antigen is CRV, and the third antigen is CPV, wherein CPV is MVC or CPV-2.

The claimed invention is also drawn to a method of vaccinating a puppy against at least one of CHV, CRV, CPV, wherein CPV is MVC or CPV-2, comprising the steps of administering a vaccine to a bitch prior to whelp and allowing the puppies to nurse, wherein the puppies nurse within 24 hours, wherein the vaccine is live, live-attenuated, inactivated, and/or any combination, and a method of vaccinating a puppy against CHV, CRV, and CPV, wherein CPV is MVC or CPV-2, comprising the steps of administering a vaccine to a bitch prior to whelp and allowing the puppies to nurse within 48 hours to transfer maternal antibodies, or nurse within 24 hours.

The claimed invention is also drawn to a multivalent vaccine able to administer to a bitch prior to whelp comprising a first antigen of CHV, a second antigen of CRV, and a third antigen of CPV, wherein CPV is MVC or CPV-2, wherein the effective amount of maternal antibodies to each antigen is transferred at nurse to the puppies, wherein the

first, second and third antigens are different, wherein the antigens are live, attenuated live, killed, and/or any combination, wherein the puppies nurse with 24 to 48 hours from whelp.

Poulet et al. teaches a canine herpesvirus 1 (CHV-1) vaccine administered to pregnant bitches 10 days after mating and again six weeks later as set forth *supra*. (Abstract).

Pratelli et al. teaches a commercial modified-live canine parvovirus type-2 (CPV-2) vaccine administered to bitches before mating and to the pups at 5 weeks and 7 weeks of age (p. 274).

Mochizuki et al. teaches that canine rotavirus (CRV) has been a secondary cause of enteric viral pathogens in dogs and detected in diarrhea specimens by cell culture and antigen assays (p. 573).

Miller et al. teaches a vaccine composition containing canine antigens, e.g., canine rotavirus as well as others (column 7, lines 49-55).

Schwartz et al. teaches the canine minute virus, also known as the minute virus of canine (MCV) is a parvovirus, which is genetically distinct from canine parvovirus type-2 (CPV-2), that causes diseases associated with reproductive failure, fetal infections, neonatal respiratory disease and enteritis in puppies and older dogs (p. 219).

Because Poulet teaches vaccination of pregnant bitches for canine herpesvirus, and Pratelli teaches immunization of pups with maternally derived antibodies for the canine parvovirus-2, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to combine the two common

pathogenic viruses into a single vaccine. As set forth *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980), It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose...the idea of combining them flows logically from their having been individually taught in prior art.

Furthermore, one of ordinary skill in the art at the time the invention was made would also have found it prima facie obvious to have added antigens for canine rotavirus because Mochizuki teaches that canine rotavirus is an important enteric pathogen for dogs. The person of ordinary skill in the art at the time the invention was made would also have found it prima facie obvious to have included specific antigens for MVC or CPV-1 and/or CPV-2 because Schwartz teaches that both viruses are pathogenic in dogs and are genetically distinct. The person of ordinary skill in the art would have been motivated to make those modifications as a convenient vaccine for breeders and canine kennels, and reasonably would have expected success because of the teachings of Miller teaching multiple canine virus antigens in a vaccine composition.

Regarding claims 7 and 26, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to nurse within 24 and 48 hours from whelp because it is necessary for survival of the pups. It would have been obvious to the skilled artisan to administer the colostrums to the puppy because of the importance of receiving the maternal antibodies from their mother.

Claims 8-13 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Poulet et al., Mochizuki et al., Schwartz et al., and Pratelli et al., as applied to claims 1-7, 14-16, and 23-27 above, and further in view of Willem et al., (Revue de Medecine Veterinaire, 2001, Vol. 152, No. 5, p. 373-378).

The claimed invention is as described above wherein the vaccine titer of the CHV, CRV, and MCV one week after whelp is greater than 1:32, and after two weeks post whelp is greater than 1:128, wherein the method of vaccinating a puppy wherein the titer of CHV, and MCV one week and two week post whelp is greater than 1:32, and CRV at one week and two week post whelp is 1:128.

As set forth *supra*, the combination of Poulet et al., Mochizuki et al., Schwartz et al., and Pratelli et al. teach a multivalent vaccine for canine herpesvirus, canine rotavirus and canine parvovirus types 1 and 2 administered to pregnant bitches for protection of the pups. While Poulet teaches high antibody titers in the vaccinated bitches, none teach the achievement of specific titers.

Willem et al. teaches the efficacy of a high titer attenuated canine parvovirus vaccine in 4-8 week old pups (p. 373). Wilem teaches the achievement of protective antibody titers in the range of $\leq$ 64 and $\geq$ 128 (p. 376, second column). Therefore Willem teaches the limitations of the claims of a post vaccination titer of greater than 1:32 and greater than 1:128.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

June 22, 2006

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